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**From:** Goodis, Michael [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=50ED0B92DC4945B7A808FE8DBC9224F0-MICHAEL GOODIS]  
**Sent:** 7/30/2019 6:55:41 PM  
**To:** Keigwin, Richard [Keigwin.Richard@epa.gov]  
**Subject:** FW: Tolfenpyrad

**Importance:** High

Rick

Following up from our conversation today, it looks like we could expedite the review of the label for a CA-specific registration.

For this action, the PRIA timeframe would be 4 months. Assuming there are no issues with the label, the team could probably complete the review in a couple of weeks or so, but would be more comfortable saying less than a month.

Michael L. Goodis, P.E.  
Director, Registration Division (RD)  
Office of Pesticide Programs (OPP)

Phone 703-308-8157  
Room S7623

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**From:** Johnson, Marion <Johnson.Marion@epa.gov>  
**Sent:** Tuesday, July 30, 2019 1:28 PM  
**To:** Goodis, Michael <Goodis.Michael@epa.gov>  
**Cc:** Rosenblatt, Daniel <Rosenblatt.Dan@epa.gov>; Davis, Donna <Davis.Donna@epa.gov>  
**Subject:** RE: Tolfenpyrad  
**Importance:** High

Mike –

Since the label language accompanying the anticipated CA-state specific new product application would be more restrictive (e.g., eco mitigating language) than the currently registered federal label, we really wouldn't have very much work to do, at all. So, I would think that the registrant would propose a PRIA category of **301**, which carries a timeframe of 4 months.

When we had the conference call with CA during the first week of this month (i.e., July 2<sup>nd</sup>), we told CA that if they elected to have the registrant submit a section 3 to effect the citrus use in California, we would do everything in our power to expedite it, since it most probably would involve no more than a label review on the PM team. We most certainly would not need the entire 4 months to review a label, and if they sent us a courtesy copy of the application concurrently, we could actually start the review before the application made its way through the front end processing.

Also, keep in mind that the 24(c) option, while not preferred, was not pulled of the table for CA's consideration during the conference call. Additionally, note that the registrant Nichino was not present on the conference call with California. Nonetheless, let me know if you have additional questions.

Marion J.

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**From:** Goodis, Michael  
**Sent:** Tuesday, July 30, 2019 12:45 PM  
**To:** Johnson, Marion <[Johnson.Marion@epa.gov](mailto:Johnson.Marion@epa.gov)>  
**Cc:** Rosenblatt, Daniel <[Rosenblatt.Dan@epa.gov](mailto:Rosenblatt.Dan@epa.gov)>; Davis, Donna <[Davis.Donna@epa.gov](mailto:Davis.Donna@epa.gov)>  
**Subject:** RE: Tolfenpyrad

Marion

Rick had a question this morning regarding the proposed CA-specific Sect 3 registration.  
What work needs to be done and how long would it take to approve the registration/review labels assuming the complete package is sent to us.  
Rick is hearing that they are concerned that it would take the full 9 months to complete this review.  
I assume that is the standard time to review this type of application but we would not need that full length of time.?

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**From:** Johnson, Marion <[Johnson.Marion@epa.gov](mailto:Johnson.Marion@epa.gov)>  
**Sent:** Monday, July 08, 2019 2:29 PM  
**To:** Goodis, Michael <[Goodis.Michael@epa.gov](mailto:Goodis.Michael@epa.gov)>  
**Cc:** Davis, Kable <[Davis.Kable@epa.gov](mailto:Davis.Kable@epa.gov)>; Rosenblatt, Daniel <[Rosenblatt.Dan@epa.gov](mailto:Rosenblatt.Dan@epa.gov)>  
**Subject:** RE: Tolfenpyrad

Citrus is already registered on the federal label, except for California. California is trying to work through some ecotox and aquatic concerns, and in doing so, is desiring to add more restrictive and/or additional mitigating language on their proposed state label that doesn't currently exist on the federal label.

MJJ

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**From:** Goodis, Michael  
**Sent:** Monday, July 8, 2019 2:10 PM  
**To:** Johnson, Marion <[Johnson.Marion@epa.gov](mailto:Johnson.Marion@epa.gov)>

**Cc:** Davis, Kable <[Davis.Kable@epa.gov](mailto:Davis.Kable@epa.gov)>; Rosenblatt, Daniel <[Rosenblatt.Dan@epa.gov](mailto:Rosenblatt.Dan@epa.gov)>

**Subject:** RE: Tolfenpyrad

I don't understand how adding citrus to the label would be a restriction though.

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**From:** Johnson, Marion  
**Sent:** Monday, July 08, 2019 2:06 PM  
**To:** Goodis, Michael <[Goodis.Michael@epa.gov](mailto:Goodis.Michael@epa.gov)>  
**Cc:** Davis, Kable <[Davis.Kable@epa.gov](mailto:Davis.Kable@epa.gov)>; Rosenblatt, Daniel <[Rosenblatt.Dan@epa.gov](mailto:Rosenblatt.Dan@epa.gov)>  
**Subject:** RE: Tolfenpyrad

Mike,

Bo, Mike, Debra, Briana and I met with CA officials by phone last Tuesday (July 2, 2019) to discuss the issue. Bo mentioned to them that OPP is currently working on a policy document that will re-examine 24C regulation to make state registrations more restrictive in labeling. Because of this, it was suggested to CA that the agency would prefer the addition of citrus use for tolfepryrad via a separate and distinct Section 3 registration, rather than utilizing the 24(C) option. We are awaiting their final preference to let us know how they would prefer to proceed. We did not pull the 24(c) option from the table, but explained the reasoning behind why the agency prefers the Section 3 option. We hope to hear from them this week on how they will propose to acquire the citrus use.

Marion J.

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**From:** Goodis, Michael  
**Sent:** Monday, July 8, 2019 1:56 PM  
**To:** Johnson, Marion <[Johnson.Marion@epa.gov](mailto:Johnson.Marion@epa.gov)>  
**Cc:** Davis, Kable <[Davis.Kable@epa.gov](mailto:Davis.Kable@epa.gov)>; Rosenblatt, Daniel <[Rosenblatt.Dan@epa.gov](mailto:Rosenblatt.Dan@epa.gov)>  
**Subject:** Tolfepryrad

I have a general with Rick tomorrow morning – what is the status of CA's request to add to the label?

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